



PREPROPOSAL STATEMENT OF INQUIRY

CR-101 (June 2004)

(Implements RCW 34.05.310)

Do **NOT** use for expedited rule making

Agency: Department of Labor and Industries

Subject of possible rule making: WAC 296-20-03002 Treatment not authorized

Statutes authorizing the agency to adopt rules on this subject: RCW 51.04.020. RCW 51.04.030

Reasons why rules on this subject may be needed and what they might accomplish: This rule is being initiated in response to a lack of efficacy data on the artificial discs and the concern about safety issues with the device. To date, 76 adverse events have been reported with the FDA. Adverse events include: 1) migration of the disc resulting in removal of the disc and fusion of the vertebrae, 2) pedicle fractures on the vertebrae, 3) subsidence, or a settling or sinking of the disc into the vertebrae, and 4) nicking of a vein or artery. In addition, the disc must be placed by approaching the spine from the front, through the abdomen. Large arteries and veins, as well as important nerves, must be mobilized and moved out of the operative area. Following surgery, scar tissue can entrap those arteries, veins and nerves. Subsequent surgery to treat a disc-related problem can be very dangerous because of that scar tissue and the vital structures that it entraps.

Identify other federal and state agencies that regulate this subject and the process coordinating the rule with these agencies: Washington workers' compensation benefits as well as the benefits paid to victims of crimes are both governed by Title 51 RCW, Washington's Industrial Insurance Act. There are no other state or federal agencies responsible for interpreting and enforcing the provisions of this Act.

Process for developing new rule (check all that apply):

☐ Negotiated rule making

☐ Pilot rule making

☐ Agency study

☒ Other (describe) Parties interested in participating in the development of these rules may contact the person listed below. The public may also participate by providing written comments during the comment period or giving oral testimony at public hearings. The rule will be developed in consultation with major stakeholders and the following interested parties:

Workers' Compensation Advisory Committee

Washington State Medical Association

How interested parties can participate in the decision to adopt the new rule and formulation of the proposed rule before publication:

(List names, addresses, telephone, fax numbers, and e-mail of persons to contact; describe meetings, other exchanges of information, etc.)

Interested parties may participate by contacting Jami Lifka by

Phone: (360) 902-4941 or FAX: (360) 902-6315 or Mail: Dept. of Labor & Industries
Office of the Medical Director
PO Box 44321
Olympia, WA 98504-4321

DATE
December 20, 2005

NAME (TYPE OR PRINT)
Gary K. Weeks

SIGNATURE

TITLE
Director

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